



INTERMOUNTAIN HEALTH CARE

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane Room 1061
Rockville MD 20852

Subject: Docket Number **2004D-0343** - Draft Guidance for Industry and FDA Staff - Hospital Bed System Dimensional Guidance to Reduce Entrapment.

To Whom It May Concern:

I believe it is important to comment regarding the document referenced above. As written, this guidance document will create an expectation that hospitals and long-term care facilities inspect all of their existing (legacy) hospital beds for compliance with these dimensional limitations. Our understanding is that pilot testing of existing beds has revealed that most if not all existing beds will not meet these dimensional limitations.

The dimensional guidance has value to existing beds if it is clearly stated that the primary focus must first be clinical assessment of the patient physical condition to establish that they are vulnerable to the risk of bed entrapment. At that point, the focus of the clinical and support staff should be the assessment of the hospital bed system with a clear plan for addition or modification of that system to meet that specific patient's needs.

Intermountain Health Care (IHC) owns 24 facilities with a combined ownership of 2780 beds. We have **NOT** had any documentation indicating entrapment issues with our current inventory of beds. Retrofitting beds would cost \$1,223,000 not including the labor costs of installation. In my opinion this represents an unwarranted financial burden on the health care system, specifically IHC.

The Clinical Engineering Departments, Engineering Departments, as well as Safety Committees within IHC urge the FDA to revise the draft document to clearly identify existing (legacy) beds as not inherently "unsafe" even though they do not meet the new dimensional limits established in this document. The focus on dimensional limits must be on new beds manufactured after the implementation of this document. The focus on legacy equipment is patient assessment first, with risk mitigation efforts based on meeting that patient's need.

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